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EXAMINER

FOREMAN, JONATHAN M

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/027,154

Applicant(s)

EHR ET AL.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 8,9 and 20-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 10-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

**DETAILED ACTION*****Election/Restrictions***

1. Applicant's election with traverse of Group I, Embodiment A and Embodiment 1 in the reply filed on 11/8/04 is acknowledged. The traversal is on the ground(s) that there is no serious burden on the examiner. This is not found persuasive because where there is no disclosure of relationship between species (see MPEP § 806.04(b)), they are independent inventions and election of one invention following a requirement for restriction is mandatory even though applicant disagrees with the examiner. There is a patentable difference between the species as claimed. See MPEP § 806.04(h). Since the claims are directed to independent inventions, restriction is proper pursuant to 35 U.S.C. 121, and it is not necessary to show a separate status in the art or separate classification. Election of species should not be required if the species claimed are considered clearly unpatentable (obvious) over each other. Applicant failed to submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case the restriction is proper. The Examiner asserts that searching for the independent inventions of Embodiments A, B, C and 1 – 4 would provide a serious burden. For example, a search performed for a pressure monitoring system having an outer sheath with a single elongated slot is different from a search performed for an outer sheath having two lumens. Additionally, Applicant has asserted that claims 20 – 26 read on Embodiment A. However, claims 20 – 26 are directed to Embodiment C shown in Figures 9 and 10.

2. The requirement is still deemed proper and is therefore made FINAL.

3. Claims 8, 9 and 20 - 30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention and species, there being no allowable generic or

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linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/8/04.

### ***Information Disclosure Statement***

The information disclosure statements filed 4/8/02, 6/12/03 and 9/25/03 comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. The information disclosure statements have been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits.

### ***Claim Objections***

4. Claim 16 is objected to because of the following informalities: Line 4 states, "at least two spaced apart openings". Line 6 states, "both openings". The Examiner suggests replacing "both openings" in line 6 with "said spaced apart openings" to improve clarity.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 2, 4, 5, 10, 11, 13 and 15 – 17 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,168,703 to Kenigsberg.

In regards to claims 1, 2, 4, 5, 10, 11, 13 and 15 – 17, Kenigsberg discloses an elongated tube (22) including an opening and a closed distal end (Col. 3, lines 22 – 24), the tube being received in a

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tubular sheath (Col. 3, lines 18 – 20), the tubular sheath (12) having at least two spaced apart openings (20), the tube being slidable within the sheath to allow the opening of the tube to be aligned with the openings of the sheath (Col. 4, lines 57 – 64), the proximal end of the elongated tube is disposed outside of the proximal end of the sheath, the elongated tube comprises two markings (28), one of the markings being aligned with the proximal end of the tubular sheath when the opening of the elongated tube is aligned with one of the openings of the tubular sheath, the other of the markings being aligned with the proximal end of the tubular sheath when the opening of the elongated tube is aligned with the other opening of the sheath (Col. 3, lines 41 – 56), the proximal end of the elongated tube is connected to a pressure transducer (Col. 3, lines 24 - 27).

7. Claims 1, 2, 6, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,396,897 to Jain et al.

8. In regards to claims 1, 2, 6, 10 and 11, Jain et al. discloses an elongated tube (2) including an opening (8) and a closed distal end (5), the tube being received in a tubular sheath (1; Col. 6, lines 52 - 53), the tubular sheath (1) having at least two spaced apart openings (3, 4), the tube being slidable within the sheath, the inside surface of the tubular sheath frictionally engages the outside surface of the elongated tube (Col. 6, lines 25 – 28), the proximal end of the elongated tube is connected to a pressure transducer (Col. 7, lines 20 – 27).

9. Claims 1, 3, 6, 10 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,358,229 to Tihon.

In regards to claims 1, 3, 6, 10 and 12, Tihon discloses an elongated tube (28) including an opening (34), the tube being received in a tubular sheath (10; Col. 3, lines 30 - 33) having a closed distal end (Col. 3, lines 62 – 63), the tubular sheath (10) having at least two spaced apart openings (26, 44), the tube being slidable within the sheath, the inside surface of the tubular sheath frictionally

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engages the outside surface of the elongated tube (Col. 3, line 66 – Col. 4, line 5) to prevent fluid communication between the inside surface of the sheath and the outside surface of the tube (Col. 3, line 66 – Col. 4, line 5).

*Claim Rejections - 35 USC § 103*

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 16 – 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,396,897 to Jain et al. in view of U.S. Patent No. 4,168,703 to Kenigsberg.

In regards to claims 16 – 18, Jain et al. discloses an elongated tube (2) including an opening (8) and a closed distal end (5), the tube being received in a tubular sheath (1; Col. 6, lines 52 - 53), the tubular sheath (1) having at least two spaced apart openings (3, 4), the tube being slidable within the sheath, the inside surface of the tubular sheath frictionally engages the outside surface of the elongated tube (Col. 6, lines 25 – 28), the proximal end of the elongated tube is disposed outside of the proximal end of the sheath and is connected to a pressure transducer (Col. 7, lines 20 – 27). Jain et al. discloses making multiple pressure measurements along the same path (Abstract). However, Jain et al. fails to disclose the elongated tube comprising two markings, one of the markings being aligned with the proximal end of the tubular sheath when the opening of the elongated tube is aligned with one of the openings of the tubular sheath, the other of the markings being aligned with the proximal end of the tubular sheath when the opening of the elongated tube is aligned with the other opening of the sheath. However, Kenigsberg discloses a pressure measuring device wherein

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the elongated tube comprises two markings (28), one of the markings being aligned with the proximal end of the tubular sheath when the opening of the elongated tube is aligned with one of the openings of the tubular sheath, the other of the markings being aligned with the proximal end of the tubular sheath when the opening of the elongated tube is aligned with the other opening of the sheath (Col. 3, lines 41 – 56). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sheath as disclosed by Jain et al. to include more openings to allow for multiple measurements without disturbing the placement of the sheath and to modify the elongate tube as disclosed by Jain et al. to include the markings as taught by Kenigsberg to provide a user with an indication of the position of the tube within the sheath (Col. 3, lines 54 – 56).

12. Claims 7 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent U.S. Patent No. 4,168,703 to Kenigsberg as applied to claims 1 and 13 above, and further in view of U.S. Patent No. 6,259,938 to Zarychta et al.

In regards to claims 7 and 14, Kenigsberg fails to disclose the sheath of the pressure monitoring device comprising a radiopaque marker at a distal end thereof. However, Zarychta et al. discloses a pressure monitoring device having comprising a sheath having a radiopaque marker at a distal end thereof (Col. 4, lines 35 – 38). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sheath as disclosed by Kenigsberg to include a radiopaque marker at a distal end as taught by Zarychta et al. in order to facilitate positioning of the sheath within the patient (Col. 4, lines 31 – 33).

13. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,396,897 to Jain et al. in view of U.S. Patent No. 4,168,703 to Kenigsberg as applied to claim 16 above, and further in view of U.S. Patent No. 6,259,938 to Zarychta et al.

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In regards to claim 19, Jain et al. in view of Kenigsberg fails to disclose the sheath of the pressure monitoring device comprising a radiopaque marker at a distal end thereof. However, Zarychta et al. discloses a pressure monitoring device having comprising a sheath having a radiopaque marker at a distal end thereof (Col. 4, lines 35 – 38). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sheath as disclosed by Jain et al. in view of Kenigsberg to include a radiopaque marker at a distal end as taught by Zarychta et al. in order to facilitate positioning of the sheath within the patient (Col. 4, lines 31 – 33).


### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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